ACT EU multi-stakeholder platform annual meeting

22 October 2024, 09:30 – 17:00 (CET/CEST)
Hybrid meeting / EMA, Amsterdam, Room 1D

The success of clinical trials relies on a wide range of stakeholders and regular dialogue between all parties can help to identify and advance clinical trial methods, technology and science, as well as remove barriers. To promote collaboration across different stakeholder groups for the improvement of clinical trials in the EU, the EC-HMA-EMA initiative, Accelerating Clinical Trials in the EU (ACT EU), has established a multi-stakeholder platform (MSP). In addition, with the recent establishment of the MSP Advisory Group (MSP AG), the work of ACT EU will be continuously informed by stakeholder views knowledge and activities in the field of clinical research.

The constant engagement with key stakeholder groups aims to accelerate the improvement of the clinical trials environment in the EU by streamlining processes and reducing administrative burden and complexity.

The MSP annual meeting aims to:

- Review the key achievements of ACT EU since its inception and their impact on clinical research.
- Discuss the current clinical trials landscape, including key initiatives, and the stakeholder needs for an improved environment.

- Look to the future to visualise what success looks like for different stakeholder groups and identify quick wins that could drive rapid change.

This workshop is open to all stakeholders through the broadcast link.

ACT EU multi-stakeholder platform annual meeting agenda

Chaired by Maria Jesús Lamas Díaz (HMA/AEMPS) and Denis Lacombe (EORTC)

22 October 2024, 09:30 – 17:00 (CET/CEST)

09:30 Joining and technical checks

09:30 Welcome and opening speech

Co-chairs welcome and opening of the meeting **5'**

Welcome from the European Medicines Agency **5'**
Peter Arlett (EMA)

Opening remarks from the European Commission **5'**
Sandra Gallina (EC)

Opening remarks from the Heads of Medicines Agencies **5'**
Maria Jesús Lamas Díaz (HMA/AEMPS)

09:50 Session 1: Looking back - Overview of ACT EU delivery to date

Moderators: Peter Arlett (EMA) and Marianne Lunzer (AGES MEA, CTCG)

ACT EU update: the journey so far **10'**
Laura Pioppo (EMA)

Consolidated advice on clinical trials **20'**
Monique Al (CCMO) / Laura Oliveira (EuropaBio) / SAWP (TBD)

New CTIS transparency rules: from policy to reality **10'**
Francesca Scotti (EMA) / Christine Dehn (EHN)

The MSP Advisory Group and stakeholders' feedback **30'**
Denis Lacombe (EORTC) / Tarec El-Galaly (EHA) / Russell Wheeler (Eurordis) / Lada Leyens (EFPIA) / Anke Hövels (KWF)

11:00 Coffee break

11:20 Session 2: The current landscape for clinical trials in Europe - ACT EU and beyond

Moderators: Isabelle Clamou (EC) and Stan van Belkum (CCMO)

What do the numbers tell us? **15'**
Linda Abdelall (EC) / Katarina Nedog (EFPIA)

Exploring the dynamics of partner collaboration with ACT EU **10'**
Ana Zanoletty (EMA)

- **CTR Collaborate and CTCG action on patient involvement** **15'**
  Marianne Lunzer (CTCG), Monique Al (CTCG)
- **Clinical Trials Coordination and Advisory Group and MedEthicsEU** **15'**
  Linda Abdelall (EC) and Monique Al (MedEthicsEU)
- **COMBINE programme** **15'**
  Isabelle Clamou (EC) and Olga Tkachenko (EC)

Panel and audience discussion ***40'***
Leona Fitzgerald (ACRO)
Nikos Dedes (EATG)
Dario Trapani (ESMO)
Jacques Demotes (ECRIN)
Nathalie Seigneuret (IHI)

13:10 Lunch

14:10 Session 3: A brighter future for clinical trials in the EU: continuing the journey

Moderators: Martin O'Kane (EFPIA) and Anton Ussi (EATRIS)

The EU's Political Drive for Clinical Trials **10'**
Elmar Nimmesgern (EC) and Isabelle Clamou (EC)

Addressing stakeholder challenges - what's next? **10'**
Marianne Lunzer (CTCG) and Laura Pioppo (EMA)

Panel and audience discussion **40'**
Anke Hövels (KWF)
Seán Byrne (EUCOPE)
Juan Ventura (CPE)
Martin Kaiser (EHA)
Donato Bonifazi (TEDDY)

WHO global guidance for more effective and equitable clinical trials **10'**
Vasee Moorthy (WHO)

Q&A **10'**

15:30 Coffee break

15:50 Session 3: A brighter future for clinical trials in the EU

Moderators: Amelia Hursey (Parkinson's Europe) and Tarec El-Galaly (EHA)

Successfully embedding clinical research as part of healthcare **10'**
Josep Tabernero (Vall d'Hebron hospital)

Panel and audience discussion **40'**
Mirjam Crul (ESOP)
Anke Hövels (KWF)
Maren Koban (EuropaBio)
Juan Ventura (CPE)
Eduard Ward van Beers (UMC Utrecht)

From the theory to the practice, how will we measure success? **10'**

Jacobus van Wyk (EMA)

16:50 Closing remarks

Wrap up **10'**
Maria Jesús Lamas Díaz (HMA/AEMPS) and Denis Lacombe (EORTC)

List of moderators, panellist and speakers

Ana Zanoletty	Head of Clinical Trials Transformation workstream, European Medicines Agency (EMA)
Anke Hövels	Lead Pharmaceutical development, The Dutch Cancer Society (KWF)
Amelia Hursey	Research Manager at Parkinson's Europe
Anton Ussi	Operations & Finance Director, European infrastructure for translational medicine (EATRIS)
Christine Dehn	Manager Patient Representation & EU Affairs, German Heart Foundation PCWP, European Heart Network (EHN)
Denis Lacombe	Chief Executive Officer, European Organisation for Research and Treatment of Cancer (EORTC), stakeholder co-chair of Multi-stakeholder Advisory Group (MSP AG)
Dario Trapani	Medical oncologist at the European Institute of Oncology (IRCCS), Assistant Professor at the Department of Oncology and Haemato-Oncology of the University of Milan, member of European Society for Medical Oncology (ESMO)
Donato Bonifazi	Chief Executive Officer of Consortium for Biological and Pharmacological Evaluations (CVBF), representative of European Network of Excellence for Paediatric Research (TEDDY)
Eduard Ward van Beers	Hematologist Internist at UMC Utrecht
Elmar Nimmesgern	Policy Officer at European Commission (EC) – Directorate General for Research and Innovation (DG RTD)
Francesca Scotti	CTIS Transparency Lead, European Medicines Agency (EMA)
Isabelle Clamou	Policy Officer at European Commission (EC) – Directorate General for Health and Food Safety (DG SANTE)
Jacobus van Wyk	Co-lead on data analytics strategy, European Medicines Agency (EMA)
Jacques Demotes	Director general of the European Clinical Research Infrastructure Network (ECRIN)
Josep Tabarnero	Head of the Medical Oncology Department at the Vall d'Hebron University Hospital
Juan Ventura	Research and Patient Engagement Director at Cancer Patients Europe (CPE)
Katarina Nedog	Associate Director, Science Policy & Regulatory Affairs at European Federation of Pharmaceutical Industries and Associations (EFPIA)
Lada Leyens	Senior Director at Takeda, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)

Laura Oliveira	Senior Director for Global Regulatory Policy and Regional Lead Europe at Merck, representative of EuropaBio
Laura Pioppo	ACT EU Programme Manager, European Medicines Agency (EMA)
Linda Abdelall	Policy Officer at European Commission (EC) – Directorate General for Health and Food Safety (DG SANTE)
Leona Fitzgerald	Executive Director Regulatory Affairs at PPD, representative of Association of Clinical Research Organizations (ACRO)
Maren Koban	Director, Global Regulatory and Scientific Policy at Merck, representative of EuropaBio
Maria Jesús Lamas Díaz	Executive Director, Spanish Agency of Medicines and Medical Products (AEMPS), Heads of Medicines Agencies (HMA), regulatory co-chair of Multi-stakeholder Advisory Group (MSP AG)
Marianne Lunzer	PV und CT Safety Assessor at Austrian Medicines and Medical Devices Agency (AGES MEA) and Chair of Clinical Trials Coordination Group (CTCG)
Martin Kaiser	Reader in Molecular Haematology and Consultant Haemato-Oncologist, Institute of Cancer Research & Royal Marsden Hospital, member of The European Haematology Association (EHA)
Martin O'Kane	Regional Head RA EU Policy & Liasion at Novartis, representative of European Federation of Pharmaceutical Industries and Associations (EFPIA)
Mirjam Crul	Physician, Clinical pharmacology and pharmacy at Amsterdam University Medical Center, representing European Society of Oncology Pharmacy(ESOP)
Monique Al	Coordinating/special advisor at Dutch Central Committee on Research Involving Human Subjects (CCMO), vice-chair Clinical Trials Coordination Group (CTCG), CTCG ethics advisory group, co-chair of MedtEthicsEU
Nathalie Seigneuret	Senior Scientific Project Manager at Innovative Health Initiative (IHI)
Nikos Dedes	Chair of the Greek Patients' Association, chair of Positive Voice, representative of European AIDS Treatment Group (EATG)
Olga Tkachenko	Policy Officer at European Commission (EC) – Directorate General for Health and Food Safety (DG SANTE)
Peter Arlett	Head of Data Analytics and Methods Task Force, European Medicines Agency (EMA)
Russell Wheeler	Patient advocate at Rare Diseases Europe (Eurordis)
Sandra Gallina	Director-General, Directorate-General Health and Food Safety (Sante) at the European Commission (EC)
Seán Byrne	Senior Manager for Legal & Regulatory Affairs at European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

Stan van Belkum	Director of the Central Committee on Research Involving Human Subjects (CCMO)
Tarec El-Galaly	Clinical professor and consultant haematologist, Aarhus University Hospital and Aarhus University, member of The European Haematology Association (EHA)
Vasee Moorthy	Senior Advisor, R&D, World Health Organisation (WHO)